Docket: 00-0238

CLAIMS:

1. A method of using microparticles to protect pharmaceutical effectiveness of a pharmaceutically active agent comprising:

providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and microparticles; and

exposing said pharmaceutically acceptable suspension to a component or condition that is incompatible with said pharmaceutically active agent, wherein said microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent that is greater than a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles.

SUB A1)

2. The method of claim 1, wherein said pharmaceutically acceptable suspension is exposed to a component comprising a metal.

3. The method of claim 2, wherein said metal is selected from stainless steel and nickel-titanium superalloy.

4. The method of claim 1, wherein said pharmaceutically acceptable suspension is exposed to a component comprising a polymer.

SUB A2)

5. The method of claim 4, wherein said polymer is selected from polyether ether ketone, polyimide, epoxy, nylon, acrylonitrile/butadiene/styrene polymers and polycarbonate.

6. The method of claim 1, wherein said pharmaceutically acceptable suspension is exposed to a freeze-thaw cycle.

7. The method of claim 1, wherein said microparticles result in a pharmaceutical effectiveness of the pharmaceutically active agent that is at least 10% greater than a pharmaceutical effectiveness of the pharmaceutically active agent in the absence of the microparticles.

8. The method of claim 1, wherein said microparticles are polymer microparticles.

SUB A3)

9. The method of claim 1, wherein said microparticles are polystyrene microparticles.

10. The method of claim 1, wherein said microparticles range from 0.01 to 100 microns in largest dimension.

11. The method of claim 1, wherein the microparticles range from 0.1 to 10 microns in largest dimension.

12. The method of claim 1, wherein the microparticles are provided in an amount of 0.1 to 1 wt% in said suspension.

13. The method of claim 1, wherein the pharmaceutically active agent comprises a polynucleotide.

14. The method of claim 13, wherein the pharmaceutically active agent is a cell, a plasmid or a viral vector.

15. The method of claim 14, wherein the pharmaceutically active agent is a viral vector selected from an adenoviral vector and an adeno-associated viral vector.

16. The method of claim 1, wherein said microparticles are polymer microparticles and wherein said pharmaceutically active agent comprises a polynucleotide.

SUB A4)

17. The method of claim 16, wherein said microparticles are polystyrene microparticles and wherein said pharmaceutically active agent is selected from a cell, a plasmid and a viral vector.

18. A method of treatment comprising:

providing a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and microparticles;

providing a medical device having a component that is incompatible with said pharmaceutically active agent; and

parenterally injecting said pharmaceutically active agent into a patient from said device while at the same time removing said microparticles from said pharmaceutically acceptable suspension.

19. The method of claim 18, wherein said microparticles are polymer microparticles.

20. The method of claim 18, wherein said microparticles are polystyrene microparticles.

21. The method of claim 18, wherein the microparticles range from 0.1 to 10 microns in largest dimension.

22. The method of claim 18, wherein the pharmaceutically active agent comprises a polynucleotide.

23. The method of claim 22, wherein the polynucleotide is provided within a cell, a plasmid or a viral vector.

24. The method of claim 18, wherein said device is a parenteral injection device selected from a vascular catheter and a syringe.

25. A pharmaceutically acceptable suspension comprising:

a pharmaceutically active agent; and

microparticles, wherein said microparticles are provided to prevent a substantial reduction in pharmaceutical effectiveness of said pharmaceutically active agent upon being exposed to a material or condition that is incompatible with said pharmaceutically active agent.

26. The pharmaceutically acceptable suspension of claim 25, wherein said microparticles are polymer microparticles.

27. The pharmaceutically acceptable suspension of claim 25, wherein said microparticles are polystyrene microparticles.

28. The pharmaceutically acceptable suspension of claim 25, wherein the microparticles range from 0.1 to 10 microns in largest dimension.

29. The pharmaceutically acceptable suspension of claim 25, wherein the pharmaceutically active agent comprises a polynucleotide.

30. The pharmaceutically acceptable suspension of claim 29, wherein the polynucleotide is provided within a cell, a plasmid or a viral vector.

31. An ampoule containing the pharmaceutically acceptable suspension of claim 25.

32. A device for parenteral injection comprising:

a pharmaceutically acceptable suspension comprising a pharmaceutically active agent and microparticles;

a device component that contacts said suspension and is incompatible with said pharmaceutically active agent; and

a separator, said separator acting to remove said microparticles from said pharmaceutically acceptable suspension prior to parenteral injection.

33. The device of claim 32, wherein said microparticles are polymer microparticles.

34. The device of claim 32, wherein the microparticles range from 0.1 to 10 microns in largest dimension.

35. The device of claim 32, wherein the pharmaceutically active agent comprises a polynucleotide.

36. The device of claim 32, wherein said device is a parenteral injection device selected from a vascular catheter and a syringe.

ADD A5